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Attorneys for Plaintiffs
Horizon Pharma AG and Jagotec AG

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HORIZON PHARMA AG and
JAGOTEC AG

Plaintiffs.

v.

PAR PHARMACEUTICAL COMPANIES,
INC. and PAR PHARMACEUTICAL, INC.,

Defendants.

Civil Action No. _____

COMPLAINT

Plaintiffs Horizon Pharma AG and Jagotec AG (collectively, "Plaintiffs") by their undersigned attorneys, bring this action against Defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively, "Par"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, arising from Par's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Horizon's

pharmaceutical product RAYOS® prior to the expiration of United States Patent Nos. 6,488,960 ("the '960 patent"), 6,677,326 ("the '326 patent"), 8,309,124 ("the '124 patent"), 8,168,218 ("the '218 patent"), and 8,394,407 ("the '407 patent") which cover RAYOS® and its use.

THE PARTIES

2. Plaintiff Horizon Pharma AG is a company organized and existing under the laws of Switzerland, with a principal place of business at Kagenstrasse 17, CH-4153 Reinach, Switzerland.

3. Plaintiff Jagotec AG is a company organized and existing under the laws of Switzerland, with a principal place of business at Eptingerstrasse 61, CH-4132 Muttenz, Switzerland.

4. Upon information and belief, Defendant Par Pharmaceutical Companies, Inc. is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

5. Upon information and belief, Defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977, and is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc.

6. Upon information and belief, Par Pharmaceutical, Inc. is in the business of, among other activities, offering for sale, selling and/or importing copies of branded pharmaceutical products throughout the United States, including in the State of New Jersey.

7. Upon information and belief, Par Pharmaceutical, Inc. makes regulatory submissions to the United States Food and Drug Administration ("FDA"), including submissions on behalf of Par Pharmaceutical Companies, Inc.

8. Upon information and belief, Par Pharmaceutical Companies, Inc. markets and sells generic drugs throughout the United States, and in particular within this judicial district, and therefore Par Pharmaceutical Companies, Inc. has engaged in systematic and continuous business within this judicial district. In addition, and upon information and belief, Par Pharmaceutical Companies, Inc. controls and dominates Par Pharmaceutical, Inc., and thus the activities of Par Pharmaceutical, Inc. in this judicial district are attributable to Par Pharmaceutical Companies, Inc.

9. Upon information and belief, Par Pharmaceutical, Inc. alone and through its parent Par Pharmaceutical Companies, Inc., markets and sells generic drugs throughout the United States, and in particular within this judicial district, and therefore Par Pharmaceutical, Inc. has engaged in systematic and continuous business within this judicial district.

10. Upon information and belief, Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. collaborated in the research and development of Par's Abbreviated New Drug Application ("ANDA") No. 204700 for delayed-release tablets that contain 2 mg and 5 mg of prednisone as the active ingredient ("the Par ANDA Products"), continue to collaborate in seeking approval of that application by the FDA, and intend to collaborate in the commercial manufacture, marketing, offer for sale and sale of the Par ANDA Product throughout the United States, including in the State of New Jersey, in the event the FDA approves Par's ANDA.

11. Upon information and belief, Par Pharmaceutical Companies, Inc. is registered to do business in New Jersey under Business I.D. No. 0100946477.

12. Upon information and belief, Par Pharmaceutical, Inc. is registered to do business in New Jersey under Business I.D. No. 0100071541, and is a registered manufacturer and wholesaler of drugs in the State of New Jersey under Registration Nos. 5001143 and 5004032, respectively.

13. Upon information and belief, Par Pharmaceutical Companies, Inc. and/or Par Pharmaceutical, Inc. did not object to personal jurisdiction or venue in the District of New Jersey and purposefully availed itself of the jurisdiction in this district by filing suit in this Court in at least Par *Pharmaceutical, Inc. et al. v. Breckenridge Pharmaceutical, Inc.*, No. 1:13-cv-04000, and by filing counterclaims in this Court in at least *Purdue Pharmaceutical Prods. L.P. et al. v. Par Pharmaceutical, Inc.*, Civil Action Nos. 2:12-cv-06738; *Medeva Pharma Suisse A.G. et al. v. Par Pharmaceutical, Inc.*, No 3:10-cv-04008; and *Depomed Inc. v. Impax Labs., Inc. et al.*, No. 3:12-cv-02154.

JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

15. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, their presence in New Jersey, having conducted business in New Jersey, having availed themselves of the rights and benefits of New Jersey law such that they should reasonably anticipate being haled into court in this judicial district, previously consenting to personal jurisdiction in this Court, availing themselves of the jurisdiction of this Court, and having engaged in systematic and continuous contacts with the State of New Jersey

through the marketing and sales of generic drugs throughout the United States, and in particular within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products, including Par Pharmaceutical, Inc. products, within this judicial district, and through their intent to market and sell the Par ANDA Products, if approved, to residents of this judicial district.

16. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENTS-IN-SUIT

17. On December 3, 2002, the U.S. Patent and Trademark Office ("PTO") duly and legally issued the '960 patent titled "Corticosteroid Formulation." At the time of its issue, the '960 patent was assigned to Arakis, Ltd., Babraham Hall, Babraham, Cambridge, United Kingdom (now known as Sosei R&D Ltd., Chesterford Research Park, Little Chesterford, Saffron Walden, Essex, United Kingdom), which later assigned the '960 patent to Nitec Pharma AG (now known as Horizon Pharma AG), Kagen-Strasse 17, Reinach Switzerland CH-4153. Horizon Pharma AG is the sole current assignee of the '960 patent, which discloses and claims, *inter alia*, a pharmaceutical composition containing prednisone. A true and correct copy of the '960 patent is attached hereto as Exhibit A.

18. On January 13, 2004, the PTO duly and legally issued the '326 patent titled "Corticosteroid Formulation Comprising Less Than 2.5 mg Prednisolone for Once Daily Administration." At the time of its issue, the '326 patent was assigned to Arakis, Ltd., Chesterford Research Park, Little Chesterford, Saffron Walden, Essex, United Kingdom (now known as Sosei R&D Ltd., Chesterford Research Park, Little Chesterford,

Saffron Walden, Essex, United Kingdom), which later assigned the '960 patent to Nitec Pharma AG (now known as Horizon Pharma AG), Kagen-Strasse 17, Reinach Switzerland CH-4153. Horizon Pharma AG is the sole current assignee of the '326 patent, which discloses and claims, *inter alia*, a pharmaceutical composition containing prednisone. A true and correct copy of the '326 patent is attached hereto as Exhibit B.

19. On November 13, 2012, the PTO duly and legally issued the '124 patent titled "Delayed Release Tablet with Defined Core Geometry." Jagotec AG is the sole current assignee of the '124 patent, which discloses and claims, *inter alia*, a pharmaceutical composition containing prednisone. A true and correct copy of the '124 patent is attached hereto as Exhibit C.

20. On May 1, 2012, the PTO duly and legally issued the '218 patent titled "Delayed Release Tablet with Defined Core Geometry." Jagotec AG is the sole current assignee of the '218 patent, which discloses and claims, *inter alia*, a pharmaceutical composition containing prednisone. A true and correct copy of the '218 patent is attached hereto as Exhibit D.

21. On March 12, 2013, the PTO duly and legally issued the '407 patent titled "Delayed Release Tablet with Defined Core Geometry." Jagotec AG is the owner of the '407 patent, which discloses and claims, *inter alia*, a pharmaceutical composition containing prednisone. A true and correct copy of the '407 patent is attached hereto as Exhibit E.

RAYOS®

22. Horizon Pharma, Inc. is the owner of the approved New Drug Application No. 202020 ("the RAYOS® NDA") for prednisone delayed-release tablets in 1 mg,

2 mg, and 5 mg dosage strengths, which are sold by Horizon Pharma USA, Inc. under the trade name RAYOS®. The RAYOS® tablets are currently approved for use as an anti-inflammatory or immunosuppressive agent for certain allergic, dermatologic, gastrointestinal, hematologic, ophthalmologic, nervous system, renal respiratory, rheumatologic, specific infectious diseases or conditions and organ transplantation; for the treatment of certain endocrine conditions; and for palliation of certain neoplastic conditions.

23. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '960, '326, '124, '218 and '407 patents are listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the RAYOS® NDA.

24. The '960 and '326 patents are listed in the Orange Book for the 1 mg and 2 mg strength RAYOS® tablets. The '124 and '407 patents are listed in the Orange Book for the 1 mg, 2 mg, and 5 mg strength RAYOS® tablets. The '218 patent is listed in the Orange Book for the 5 mg strength RAYOS® tablets.

25. The '960, '326, '124, '218 and '407 patents cover the RAYOS® product.

PAR'S ANDA

26. On information and belief, Par Pharmaceutical, Inc. submitted ANDA No. 204700 ("the Par ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market prednisone delayed-release tablets in 2 mg and 5 mg dosage strengths. On information and belief, the Par ANDA is seeking approval to market the Par Products as an anti-inflammatory or immunosuppressive agent for certain allergic, dermatologic, gastrointestinal, hematologic, ophthalmologic, nervous system, renal respiratory,

rheumatologic, specific infectious diseases or conditions and organ transplantation; for the treatment of certain endocrine conditions; and for palliation of certain neoplastic conditions.

27. The Par ANDA refers to and relies upon the RAYOS® NDA and contains data that, according to Par, demonstrate the bioequivalence of the Par Products and RAYOS®.

28. Plaintiffs have received from Par a letter, dated September 12, 2013 (the "Par Notification"), stating that Par had included a certification in the Par ANDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '960, '326, '124, '218 and '407 patents are invalid or will not be infringed by the commercial manufacture, use or sale of the Par Products (the "Paragraph IV Certification").

COUNT I FOR INFRINGEMENT OF U.S. PATENT 6,488,960

29. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-28 of this Complaint.

30. Defendants have infringed the '960 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA, by which Defendants seek approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Par Products in 2 mg dosage strength prior to the expiration of the '960 patent.

31. Defendants' commercial manufacture, use, offer to sell, or sale of the Par Products within the United States, or importation of the Par Products in 2 mg dosage strength into the United States during the term of the '960 patent would further infringe the '960 patent under 35 U.S.C. § 271(a), (b) and/or (c).

32. This action is being filed within 45 days of receipt by Plaintiffs of the Par Notification dated September 12, 2013, which purportedly advised Plaintiffs of Par's Paragraph IV Certification with respect to the '960 patent.

33. Upon information and belief, Defendants had actual and constructive notice of the '960 patent prior to filing Par's ANDA, and Defendants' infringement of the '960 patent has been, and continues to be, willful.

34. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA be a date that is not earlier than the expiration of the '960 patent, or any later expiration of exclusivity for the '960 patent to which they become entitled.

35. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '960 patent.

36. Plaintiffs have no adequate remedy at law.

37. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II FOR INFRINGEMENT OF U.S. PATENT 6,677,326

38. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-28 of this Complaint.

39. Defendants have infringed the '326 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA, by which Defendants seek approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Par Products in 2 mg dosage strength prior to the expiration of the '326 patent.

40. Defendants' commercial manufacture, use, offer to sell, or sale of the Par Products within the United States, or importation of the Par Products in 2 mg dosage strength into the United States during the term of the '326 patent would further infringe the '326 patent under 35 U.S.C. § 271(a), (b) and/or (c).

41. This action is being filed within 45 days of receipt by Plaintiffs of the Par Notification dated September 12, 2013, which purportedly advised Plaintiffs of Par's Paragraph IV Certification with respect to the '326 patent.

42. Upon information and belief, Defendants had actual and constructive notice of the '326 patent prior to filing Par's ANDA, and Defendants' infringement of the '326 patent has been, and continues to be, willful.

43. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA be a date that is not earlier than the expiration of the '326 patent, or any later expiration of exclusivity for the '326 patent to which they become entitled.

44. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '326 patent.

45. Plaintiffs have no adequate remedy at law.

46. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III FOR INFRINGEMENT OF U.S. PATENT 8,309,124

47. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-28 of this Complaint.

48. Defendants have infringed the '124 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA, by which Defendants seek approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Par Products in 2 mg and 5 mg dosage strengths prior to the expiration of the '124 patent.

49. Defendants' commercial manufacture, use, offer to sell, or sale of the Par Products within the United States, or importation of the Par Products in 2 mg and 5 mg dosage strengths into the United States during the term of the '124 patent would further infringe the '124 patent under 35 U.S.C. § 271(a), (b) and/or (c).

50. This action is being filed within 45 days of receipt by Plaintiffs of the Par Notification dated September 12, 2013, which purportedly advised Plaintiffs of Par's Paragraph IV Certification with respect to the '124 patent.

51. Upon information and belief, Defendants had actual and constructive notice of the '124 patent prior to filing Par's ANDA, and Defendants' infringement of the '124 patent has been, and continues to be, willful.

52. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA be a date that is not earlier than the expiration of the '124 patent, or any later expiration of exclusivity for the '124 patent to which they become entitled.

53. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '124 patent.

54. Plaintiffs have no adequate remedy at law.

55. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT IV FOR INFRINGEMENT OF U.S. PATENT 8,168,218

56. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-28 of this Complaint.

57. Defendants have infringed the '218 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA, by which Defendants seek approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Par Products in 5 mg dosage strength prior to the expiration of the '218 patent.

58. Defendants' commercial manufacture, use, offer to sell, or sale of the Par Products within the United States, or importation of the Par Products in 5 mg dosage strength into the United States during the term of the '218 patent would further infringe the '218 patent under 35 U.S.C. § 271(a), (b) and/or (c).

59. This action is being filed within 45 days of receipt by Plaintiffs of the Par Notification dated September 12, 2013, which purportedly advised Plaintiffs of Par's Paragraph IV Certification with respect to the '218 patent.

60. Upon information and belief, Defendants had actual and constructive notice of the '218 patent prior to filing Par's ANDA, and Defendants' infringement of the '218 patent has been, and continues to be, willful.

61. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA be a date that is not earlier than the expiration of the '218 patent, or any later expiration of exclusivity for the '218 patent to which they become entitled.

62. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '218 patent.

63. Plaintiffs have no adequate remedy at law.

64. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT V FOR INFRINGEMENT OF U.S. PATENT 8,394,407

65. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-28 of this Complaint.

66. Defendants have infringed the '407 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA, by which Defendants seek approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Par Products in 2 mg and 5 mg dosage strengths prior to the expiration of the '407 patent.

67. Par's commercial manufacture, use, offer to sell, or sale of the Par Products within the United States, or importation of the Par Products in 2 mg and 5 mg dosage strengths into the United States during the term of the '407 patent would further infringe the '407 patent under 35 U.S.C. § 271(a), (b) and/or (c).

68. This action is being filed within 45 days of receipt by Plaintiffs of the Par Notification dated September 12, 2013, which purportedly advised Plaintiffs of Par's Paragraph IV Certification with respect to the '407 patent.

69. Upon information and belief, Defendants had actual and constructive notice of the '407 patent prior to filing Par's ANDA, and Par's infringement of the '407 patent has been, and continues to be, willful.

70. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA be a date that is not earlier than the expiration of the '407 patent, or any later expiration of exclusivity for the '407 patent to which they become entitled.

71. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '407 patent.

72. Plaintiffs have no adequate remedy at law.

73. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

74. WHEREFORE, Horizon Pharma AG and Jagotec AG pray for a judgment in their favor against Defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., and respectfully request the following relief:

A. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent 6,488,960;

B. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent 6,677,326;

C. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent 8,309,124;

D. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent 8,168,218;

E. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent 8,394,407;

F. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Par Products in 2 mg dosage strength within the United States, or importing the Par Products into the United States, prior to the expiration date of the '960 patent;

G. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Par Products in 2 mg dosage strength within the United States, or importing the Par Products into the United States, prior to the expiration date of the '326 patent;

H. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Par Products in 2 mg and 5 mg dosage strengths within the United States, or importing the Par Products into the United States, prior to the expiration date of the '124 patent;

I. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Par Products in 5 mg dosage strength within the United States, or importing the Par Products into the United States, prior to the expiration date of the '218 patent;

J. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Par Products in 2 mg and 5 mg dosage strengths within the United States, or importing the Par Products into the United States, prior to the expiration date of the '407 patent;

K. If Defendants commercially manufacture, use, offer to sell, or sell the Par Products within the United States, or import the Par Products in 2 mg dosage strength into the United States, prior to the expiration of the '960 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

L. If Defendants commercially manufacture, use, offer to sell, or sell the Par Products within the United States, or import the Par Products in 2 mg dosage strength into the United States, prior to the expiration of the '326 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

M. If Defendants commercially manufacture, use, offer to sell, or sell the Par Products within the United States, or import the Par Products in 2 mg and 5 mg dosage

strengths into the United States, prior to the expiration of the '124 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

N. If Defendants commercially manufacture, use, offer to sell, or sell the Par Products within the United States, or import the Par Products in 5 mg dosage strength into the United States, prior to the expiration of the '218 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

O. If Defendants commercially manufacture, use, offer to sell, or sell the Par Products within the United States, or import the Par Products in 2 mg and 5 mg dosage strengths into the United States, prior to the expiration of the '407 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

P. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

Q. Costs and expenses in this action; and

R. Such other and further relief as the Court deems just and proper.

Dated: October 22, 2013

Respectfully submitted,

s/ John F. Brenner

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